## REMARKS

Claims 1, 5, 6, 8, 10, 11 and 14–17 are pending in the application. Claims 1 and 8 have been amended. Support for the amendment can be found in the specification as originally filed. No new matter has been added.

## REJECTIONS UNDER 35 USC 103

Claims 1-3, 5, 6, 8, 10, 11 and 14–17 stand rejected under 35 USC 103(a) as being unpatentable over Runnells et al. (US 3,752,145) in view of Niehoff (US 5,662,612). This rejection should be withdrawn in view of the remarks and amendments made herein.

It is well settled that to establish a *prima facie* case of obviousness, the USPTO must satisfy all of the following requirements. First, the prior art relied upon, coupled with the knowledge generally available in the art at the time of the invention, must contain some suggestion or incentive that would have motivated the skilled artisan to modify a reference or to combine references. *In re Fine*, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). Second, the proposed modification does not have a reasonable expectation of success, as determined from the vantage point of one of ordinary skill in the art at the time the invention was made. *Amgen v. Chugai Pharmaceutical Co*. 18 USPQ 2d 1016, 1023 (Fed Cir, 1991), *cert. denied* 502 U.S. 856 (1991). Third, the prior art reference or combination of references must teach or suggest all of the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496, (CCPA 1970).

The Office Action alleges that Runnells teaches a method of operating an injector, including that a "tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate." Further, the Office Action alleges that "Niehoff discloses a power injector which automatically senses the presence and capacity of a syringe and advances and retracts the plunger automatically (see Abstract)."

Applicants' invention of Claim 1 has been amended to include subject matter similar to Claim 2 and to indicate that an empty syringe is mounted in the injector.

Claim 1 is directed to a method for preparing an injection procedure and includes "sensing from an encoding device that the syringe is mounted on the injector and is an empty syringe; in response to sensing the syringe, automatically advancing the piston of the injector to engage the plunger of the syringe and to advance the plunger to the distal end thereof to expel air from the syringe…" (Further, Applicants' invention of Claim 8 also includes similar subject matter, "sensing that the syringe is mounted on the injector; automatically determining based on the sensing whether the syringe is an empty syringe, a preloaded syringe or a prefilled syringe; and in response to sensing the syringe, automatically advancing the piston of the injector to engage the plunger of the syringe.")

This novel feature of Applicants' invention includes that:

> the "auto engage" feature allows an injector to automatically advance the drive piston thereof to engage a syringe plunger upon installation or attachment of the syringe to the injector. In a preferred embodiment, the auto engage feature occurs without operator intervention. This feature is particularly useful for preloaded and prefilled syringes, which typically have plungers located at some position within the syringe barrel other than at the proximal and distal ends thereof, and plunger-forward syringes. In the case of prefilled syringes, the auto engage feature automatically connects the injector piston and syringe plunger for subsequent priming of the syringe (and associated tubing) and subsequent injection. For plunger-forward syringes, the auto engage feature engages the piston and plunger for subsequent retraction of the plunger for aspiration of fluid, such as contract media, into the syringe. (Specification, page 57, para 2).

However, Niehoff is directed to computer-controlled injector that requires steps that are entirely different that Applicants' invention, namely, operator intervention of moving the plunger driver after the installation of the syringe when the syringe is empty or no advancement of the plunder driver when the computer detects physical indicia on the syringe or extender (e.g. that the syringe is prefilled or preloaded). (Col. 3, line 48 – Col. 4, line 3). In the first instance, if the syringe is an empty syringe then Neihoff requires some input beyond just sensing that the syringe has been installed in the injector. The operator must manually begin movement of the plunger drive to position the plunger drive near the plunger (col. 5, lines 1-22). In the second instance, if the syringe is prefilled or preloaded, then there will be no advancement to the plunger because the plunger drive will be positioned at the rearward end of the syringe upon

installation because in a prefilled syringe the plunger will be at the rearward end of the syringe or the extender will be at the rearward end of the syringe and in operative connection of the forward located plunger (See Fig. 1a and 1b). Therefore, no advancement will be required to get the plunger driver to engage with the plunger. Thus, Niehoff does not teach or suggest automatic advancement based on sensing that the syringe is installed.

Further, Runnells et al does not disclose sensing of the syringe when mounted and automatically advancing the piston of the injector based on the sensing. Thus, neither Runnells or Niehoff, alone or in combination, teach or suggest Applicants' invention of Claims 1 or 8.

Claims 1 and 8 are also directed to the method and includes "advancing the piston to prime the fluid path for the injection procedure." Applicants' invention includes this novel feature that:

> The "auto prime" feature allows an injector to automatically prime the fluid path (i.e., syringe and connecting tubing) before an injection procedure. Preferably, the volume of fluid contained within a connector tubing used with a syringe is pre-programmed into the injector. For example, a 60' low pressure connecting tubing ("LPCT") provided by Medrad, Inc., the Assignee of the present application, for use with its disposable syringes typically holds approximately 2.78 ml of fluid. Alternately, the operator may manually program the fluid volume contained within the connector tube into the injector.
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> As will become apparent, the auto prime feature may be functionally dependent, in certain respects, on the auto fill feature…. When a syringe is filled with fluid (i.e., by means of the auto fill feature), the injector automatically compensates for the connector tube by adding its corresponding fluid volume to the fluid volume desired by the operator to be aspirated into the syringe for an injection operation. For example, if the operator desires to fill the syringe with 150ml of fluid for an injection procedure, the auto fill feature will compensate for the connector tube fluid volume by automatically adding 2.78 ml of fluid (e.g., for a 60' LPCT), for a total volume of 152.78 ml aspirated into the syringe. After the syringe is filed with fluid, the auto prime feature would then cause the injector piston to advance the syringe plunger to the extent necessary to expel air from the syringe and connector tube system, preferably without prompting by the operator. Once the auto prime function is conducted, fluid should be present at the patient end of the connector tube (i.e., the end that is connected to the catheter). (Specification, page 59, para 3).

As can be appreciated, the auto prime feature may save operator time and reduce the amount of wasted fluid. By automatically compensating for the fluid contained within

the connector tube, the operator does not have to vigilantly watch the progression of the fluid from the syringe through the connecting tube in order to stop the advancement of the piston before a significant amount of fluid is discharged from the end of the connector tubing. Also, because some operators of conventional injectors advance the piston quickly to lessen the time required to prime the syringe and tubing system, often a significant amount of fluid will be expelled from the end of the connector tubing before the operator stops the piston's advancement. If a sufficient amount of contrast is expelled, the syringe may have to be re-filled (and the syringe and tubing system subsequently re-primed) to insure that it contains a sufficient amount of fluid for the required injection procedure. (Specification, page 59, para 3 to page 60, para 1).

Although the Office Action alleges that Runnells teaches "…Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22," there is no teaching or suggestion of Applicants' invention. Rather, Runnells is limited to one in which:

> "[c]ontrast solution is poured into the syringe housing and the head 40 is replaced. A tube is then attached to the outlet 22 of the syringe and the free end of the tube is submerged in contrast solution. Air is bled from the syringe by advancing the piston plate 14 toward the outlet 22. Additional contrast solution may then be drawn through the tube into the syringe housing by retracting the piston plate. The contents of the safety chamber 46 may then be viewed through the transparent wall 42 of the magnifying safety head. If bubbles are noted, the piston plate is advanced and retracted once more to expel the entrapped air and to replace the desired volume of contrast solution. The contents of the safety chamber are again viewed, and the piston plate may again be advanced and retracted as often as necessary until no bubbles are observed through the magnifying walls 42 of the head 40.
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> Sometimes it is convenient to eliminate the step of filling the syringe housing through the tip end, but in any event, the presence of entrapped air is determined by visual observation with the magnifying head up and the syringe as nearly vertical as possible, and after all observed air is expelled, injections should be given with the outlet down and the syringe as nearly vertical as the angiographic procedure permits. (col. 3, lines 4-28).

Thus, Runnells requires operator intervention, with visual observation, and thus teaches away from Applicants' invention of Claims 1 and 8. Thus Runnells does not teach or suggest Applicants' invention of Claims 1 or 8, and Niehoff fails to cure the deficiencies of Runnells. Accordingly, Claims 1 and 8 are believed to be patentable over Runnells in view of Niehoff. Reconsideration is requested.

Regarding Claim 11, Claim 11 includes "advancing the piston to prime the syringe and a tube connected to the syringe, wherein the priming is based on a fluid volume of the tube." As discussed above, Runnells teaches that air is bled from a syringe, but it is limited to operator involvement, including visual observation. Additionally, Runnells is limited to observing air bubbles. (See Col. 3, lines 4-28). Further, Niehoff either alone or in combination, does not teach or suggest Applicants' invention. Reconsideration of Claim 11 is requested.

Regarding Claim 14, claim 14 includes that the priming is based on a predetermined amount. Neither, Runnells nor Niehoff teach or suggest Applicants' invention. Accordingly, reconsideration of Claim 14 is requested.

Regarding Claim 17, Claim 17 is directed to "advancing the piston during the step of retracting the piston to retract the plunger and aspirate fluid…" However, neither Runnells nor Niehoff teach or suggest this novel feature of Applicants' invention. Therefore, reconsideration is requested.

Claims 5, 6 10 and 14-16 depend, either directly or indirectly, from Claim 1, 8 and 11, which as discussed herein is believed to be allowable. Thus, Claims 5, 6, 10 and 14-16 are also believed to be allowable. Accordingly, reconsideration of Claims 1, 5, 6, 8, 10, 11 and 14-17 is respectfully requested.

In view of the above amendments and remarks, Applicants submit that the claims are in condition for allowance and the Examiner would be justified in allowing them.

Respectfully submitted,

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